

REMARKS

This Application has been carefully reviewed in light of the Office Action mailed March 12, 2009. At the time of the Office Action, Claims 64-98 were pending in this Application. Claims 64-70, 74-85 and 89-98 were rejected. Claims 64, 66, 67, 74, 79, 81, 82, 89, 90, 97, and 98 have been amended. Support for the claim amendments (*e.g.*, “bodily sample”) may be found in the specification as originally filed, for example, at Page 3, lines 2-4, Page 4, lines 23-26, Page 10, lines 13-15 and 25-28, Page 11, lines 7-9 and lines 26-28, Page 12, lines 3-5, Page 14, lines 13-17. Claims 71-73 and 86-88 have been withdrawn due to an election/restriction requirement. Applicant respectfully requests reconsideration and favorable action in this case.

Interview Summary

On April 27, 2009, inventor Tony Baker and counsel for assignee, Sierra Molecular, Mark Jacobs and Guy Birkenmeier met with Examiner Johannsen at her office in the Remsen Building on the U.S.P.T.O. campus in Alexandria, Virginia. Amendments to overcome the outstanding rejections under §§ 112, 102, and 103 were discussed. Examiner Johannsen indicated that:

- (a) amending claims may overcome the indefiniteness rejection;
- (b) identifying support for storage conditions may be used to overcome the written description rejection;
- (c) identifying support in the application or the literature or introducing evidence by declaration for sodium salicylate may overcome the enablement rejection; and
- (d) amending claims may overcome art rejections.

Inventor Baker indicated that sodium salicylate functions both in preservation and suppression, but appears to have a stronger preservation effect. Although no agreement was reached, Applicant indicated that an after-final amendment would be filed in short order and Examiner Johannsen indicated that she would review the amendments and

remarks and contact Dr. Birkenmeier regarding any remaining issues, as appropriate. Applicant thanks Examiner Johannsen for cordially granting Applicant an interview and for her helpful comments during the interview.

Rejections under 35 U.S.C. § 112

A. 35 U.S.C. §112, Second Paragraph

Claims 64-70 and 74-78 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Applicant respectfully traverses and asserts that Claims 64-70 and 74-78, as amended herein, are clear and definite. Therefore, Applicant respectfully requests withdrawal of this rejection.

B. 35 U.S.C. §112, First Paragraph

Claims 64-70, 74-85 and 89-98 have been rejected by the Examiner under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Applicant respectfully traverses and asserts that Claims 64-70, 74-85 and 89-98 are fully described in the application as originally filed. For Example, support for “storing the sample” may be found in the specification as originally filed, for example, at Page 11, line 30 to Page 12, line 2 (7 days at 4° C), Page 12, lines 3-5 (48 hours at 20° C), Page 17, lines 27-28 (8 hours at room temperature).

Claims 64-70, 74-85 and 89-98 have been rejected by the Examiner under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicant respectfully traverses and asserts that Claims 64-70, 74-85 and 89-98 are fully enabled by the application as originally filed. For example, the Specification on page 3, lines 15-19, recites:

The masking agents that are present in a nucleic acid-containing test sample are suppressed by contacting the test sample with an amount of one or more divalent metal chelators like ethylenediaminetetraacetic acid or 1,2-bis(2-aminophenoxy)ethane-N,N,N',N'-tetraacetic acid, or salts thereof; and an amount of one or more chelator enhancing components like lithium chloride, guanidine, or **sodium salicylate**.

(**emphasis added**). In addition, the Specification on page 4, lines 6-10, recites:

A further aspect of the invention relates to methods of improving hybridization of nucleic acids, including contacting a test nucleic acid with a reagent comprising an amount of at least one divalent metal chelator, e.g., in the range of from about 0.001M to 0.1M; and an amount of at least one chelator enhancing component, e.g., lithium chloride, guanidine, **sodium salicylate**, sodium perchlorate, or sodium thiocyanate....

(**emphasis added**). Furthermore, the Specification on page 6, lines 29-30, recites:

Lithium chloride, guanidine, **sodium salicylate**, sodium perchlorate, and sodium thiocyanate have been found to be particularly effective.

(**emphasis added**).

In addition, Applicant respectfully invites the Examiner's attention to Examples 6 and 7 of U.S. Patent No. 6,458,546 ("the '546 patent")¹, which shares with the instant application a priority claim to U.S. Application No. 09/805,785. The '546 patent is concurrently cited in an Information Disclosure Statement filed herewith. Example 6 discloses that a composition including sodium salicylate functions in preservation. Example 7 discloses that compositions of the invention, which would include sodium salicylate compositions, enhanced PCR results obtained with samples containing suspended *Neisseria gonorrhea*.

In light of these disclosures and the level of ordinary skill in the art, nothing more than reasonable experimentation would have been required to use sodium salicylate (e.g., in place of any of the other disclosed chelator enhancing components) to suppress interference by a masking agent. Therefore, since the specification fully supports using sodium salicylate as chelator enhancing component, Applicant respectfully requests withdrawal of the instant enablement rejection.

Rejections under 35 U.S.C. § 102

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

¹ The published U.S. application, U.S. Patent Publication No. 2002/0102580, corresponding to the '546 patent was made of record in the instant application in an Information Disclosure Statement filed on October 18, 2007.

Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, “the identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co. Ltd.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). Applicant respectfully submits that the art cited as anticipatory by the Examiner cannot anticipate the rejected Claims, because the cited art does not show all the elements of the present Claims.

A. Claims 64-70, 75, 77-78, and 97-98

Claims 64-70, 75, 77-78, and 97-98 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,514,551 issued to Yeasing Yang *et al.* (“Yang”) Applicant respectfully traverses and submits the cited art does not teach all of the elements of the presently claimed embodiments.

Claims 64-70, 75, 77-78, and 97-98, as amended herein, recite a “bodily sample.” *Yang* fails to teach “contacting the bodily sample with a reagent” as presently claimed. On the contrary, Example 1 of *Yang* recites “purified *C. trachomatis* (ATCC No. VR-886) rRNA.” See *Yang*, Col. 20, lines 39-40. Therefore, Applicant respectfully submits that *Yang* cannot anticipate the instant claims and requests withdrawal of the 35 U.S.C. §102(b) rejections to Claims 64-70, 75, 77-78, and 97-98.

B. Claims 64-70, 74-76, 79-85, 89, 93-94, and 97-98

Claims 64-70, 74-76, 79-85, 89, 93-94, and 97-98 stand rejected under 35 U.S.C. §102(b) as being anticipated by “*An Improved Method for Isolating High Quality Polysaccharide-free RNA from Tenacious Plant Tissues*,” by Chung Han Chung *et al.* (“Chung”). Applicant respectfully traverses and submits the cited art does not teach all of the elements of the claimed embodiment of the invention.

Claims 64-70, 74-76, 79-85, 89, 93-94, and 97-98, as amended herein, recite a “bodily sample.” *Chung* fails to teach “contacting the bodily sample with a reagent” as presently claimed. On the contrary, *Chung* recites “oilseed and other plant tissues.” See Page 109, left column, ¶ 8. Therefore, Applicant respectfully submits that *Yang* cannot

anticipate the instant claims and requests withdrawal of the 35 U.S.C. §102(b) rejections to Claims 64-70, 74-76, 79-85, 89, 93-94, and 97-98.

Rejections under 35 U.S.C. § 103

In order to establish a *prima facie* case of obviousness, the references cited by the Examiner must disclose all claimed limitations. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Even if each limitation is disclosed in a combination of references, however, a claim composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int'l. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). Rather, the Examiner must identify an apparent reason to combine the known elements in the fashion claimed. *Id.* “Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.*, citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). Finally, the reason must be free of the distortion caused by hindsight bias and may not rely on ex post reasoning. *KSR*, 127 S.Ct. at 1742. In addition, evidence that such a combination was uniquely challenging or difficult tends to show that a claim was not obvious. *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc. and Mattel, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007), citing *KSR*, 127 S.Ct. at 1741.

Claims 67, 77-78, 82, and 95-96 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Chung* in view of *Yang*. Applicant respectfully traverses and submits the cited art combinations, even if proper, which Applicant does not concede, does not render the claimed embodiment of the invention obvious. As noted in the preceding section, Claims 67, 77-78, 82, and 95-96, as amended herein, recite “bodily fluid,” which is not taught or suggested by any of the cited portions of *Yang* or *Chung*, whether considered alone or in combination.

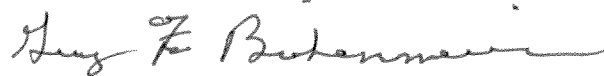
CONCLUSION

Applicant has made an earnest effort to place this case in condition for allowance in light of the amendments and remarks set forth above. Applicant respectfully requests reconsideration of the pending claims.

Applicants believe there are no further fees due at this time, however, the Commissioner is hereby authorized to charge any fees necessary or credit any overpayment to Deposit Account No. 50-4871 of King & Spalding L.L.P.

If there are any matters concerning this Application that may be cleared up in a telephone conversation, please contact Applicant's attorney at 512.457.2000.

Respectfully submitted,
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